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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/684,229	10/10/2003	Lin Zhi	45026.00128.UTL1	8639

20985 7590 09/01/2005

FISH & RICHARDSON, PC  
12390 EL CAMINO REAL  
SAN DIEGO, CA 92130-2081

EXAMINER
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AULAKH, CHARANJIT

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 09/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/684,229

**Applicant(s)**

ZHI ET AL.

**Examiner**

Charanjit S. Aulakh

**Art Unit**

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 July 2005.  
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 2-16, 18-28 and 30-47 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☒ Claim(s) 12 and 13 is/are allowed.  
6) ☒ Claim(s) 9-11, 14, 15, 18-22, 24-28 and 30-46 is/are rejected.  
7) ☒ Claim(s) 2-8, 16, 23 and 47 is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_.

5-20

### **DETAILED ACTION**

1. According to paper filed on July 5, 2005, the applicants have canceled claims 1, 17 and 29; amended claims 2-6, 8-13, 15, 18-22, 24-28, 30, 33-35, 41 and 43 and furthermore, have added new claims 44-47.
2. Claims 2-16, 18-28 and 30-47 are now pending in the application.

### ***Response to Arguments***

3. Applicant's arguments filed on July 5, 2005 have been fully considered but they are not persuasive regarding enablement as well as indefiniteness rejections. In regard to enablement rejection, the examiner does not agree with the applicants arguments that it would not require undue experimentation. As stated clearly in the last office action, the instant compounds are agonists at progesterone receptors and therefore, will have utility in treating only those disease conditions where progesterone receptor agonists were well known in the prior art before effective filing date of instant application to have therapeutic utility. The examiner also does not agree with the applicants arguments regarding the term --prodrugs--. There are numerous ways for preparing prodrugs in the art and furthermore, there is lot of unpredictability regarding availability of parent compound of different prodrugs to its target in vivo since it is influenced by various factors such as absorption, metabolism, degradation by esterases etc. In regard to indefiniteness rejections, the examiner does not agree with the applicants arguments that the terms --- prodrugs, modulating, condition mediated by progesterone, type of

cancer treated etc.--- are definite terms. The examiner also does not agree with the applicants arguments regarding instant claim 43.

***Conclusion***

4. Rejection of claims 14, 28 and 30-43 under 35 U.S.C. 112, first paragraph is maintained for the reasons of record.
5. Rejection of claims 14, 28, 30, 33, 35, 41 and 43 under 35 U.S.C. 112, second paragraph is maintained for the reasons of record.
6. Rejection under 35 U.S.C. 102(b) is now withdrawn in view of amendments of claims.

**NEW GROUNDS OF REJECTION**

7. The applicants have amended dependent claims 9-11,15, 25-27 to make them independent and furthermore, have included the term –prodrug----. Similarly, newly added claims 44-46 also have the term –prodrug--. Therefore, claims 9-11,15, 25-27 and 44-46 are also rejected under 35 U.S.C. 112, first paragraph and second paragraph for the reasons of record for this term in original claims.

***Claim Rejections - 35 USC § 112***

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 18-22 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 18-22 and 24 depend upon claims 48 and 49 which are not present in the application.

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10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

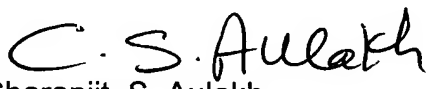
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charanjit S. Aulakh whose telephone number is (571)272-0678. The examiner can normally be reached on Monday through Friday, 8:30 A.M. to 5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571)272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Charanjit S. Aulakh  
Primary Examiner  
Art Unit 1625